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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,899	12/08/2000	Benjamin Chain	20555/1203433-US1	1183
7278	7590	11/25/2009		
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER SWARTZ, RODNEY P	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 11/25/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/731,899	Applicant(s) CHAIN, BENJAMIN	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-15,21-25 and 27-35 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 and 33-35 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-25 and 27-32 is/are allowed.
- 6) ☒ Claim(s) 1,7,10 and 11 is/are rejected.
- 7) ☒ Claim(s) 2-5,8,9 and 12 is/are objected to.
- 8) ☒ Claim(s) 1-5,7-15,21-25 and 27-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's Response to Office Action, received 21 August 2009, is acknowledged.
2. Claims 1-5, 7-15, 21-25 and 27-35 are pending. Claims 13-15 and 33-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.
3. Claims 1-5, 7-12, 21-25 and 27-32 are under consideration.

Rejections Maintained

4. The rejection of claims 1, 7, 10 and 11 under 35 U.S.C. 102(b) as being anticipated by Frazer et al (WO98/23635, 4 June 1998) is maintained for reasons of record.

Applicant argues that the cited reference does not disclose a chimeric peptide comprising the first 2-5 amino acid residues from the free N- or free C-terminus of a naturally-occurring internal peptide cleavage products that is formed by proteolytic cleavage of a precursor protein or a mature protein.

The examiner has considered applicants' argument, but does not find it persuasive. The claims are drawn to a product, i.e., a chimeric peptide of formula (I) or formula (II).

(I) is $N-(S)_m-(T_h)_n$

where N is 2, 3, 4 or 5 amino acids residues,

where S is a spacer amino acid residue,

where m is 0, 1, 2, 3, 4 or 5

where n is 1, 2, 3, or 4; and

where T_h is a promiscuous T helper cell epitope.

(II) is $(T_h)_n-(S)_m-C$

where C is 2, 3, 4 or 5 amino acids residues,

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where S is a spacer amino acid residue,

where m is 0, 1, 2, 3, 4 or 5

where n is 1, 2, 3, or 4; and

where T_h is a promiscuous T helper cell epitope.

The recitation in formula (I) that "N is the first amino acid residues from the free N-terminus of a naturally occurring internal peptide cleavage product that is formed by proteolytic cleavage of a precursor protein or a mature protein" is merely the source of the residues and does not place any patentable weight on the identity of the residues which would differentiate it from identical residues which are obtained by any other means. Thus, the requirement that N is any 2, 3, 4 or 5 amino acids residues would satisfy the product structure.

The recitation in formula (II) that "C is the last amino acid residues from the free C-terminus of a naturally occurring internal peptide cleavage product that is formed by proteolytic cleavage of a precursor protein or a mature protein" is merely the source of the residues and does not place any patentable weight on the identity of the residues which would differentiate it from identical residues which are obtained by any other means. Thus, the requirement that C is any 2, 3, 4 or 5 amino acids residues would satisfy the product structure.

As put forth in the original rejection, Frazer et al do teach a chimeric peptide which satisfies the structural requirements of formula (I).

5. The objection to claims 2-5, 8, 9 and 12 for dependence from rejected claims is maintained.

Conclusion

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6. Claims 1-5 and 7-12 are not allowed. Claims 21-25 and 27-32 appear to be free of the prior art.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 13-15 and 33-35 drawn to a non-elected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

November 25, 2009